

### **REMARKS**

By the foregoing Amendment, Claim 6 is amended. Entry of the Amendment, and favorable consideration thereof, is earnestly requested. Claims 3, 7, 9, 14 and 67 having been previously cancelled, Claims 1, 2, 4-6, 8, 10-13 and 15-66 are currently pending.

### **Rejections under 35 U.S.C § 112**

Claim 6 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner has noted that it is unclear as to whether the molecular weight referred to in Claim 6 is the weight average molecular weight (Mw) or the number average molecular weight (Mn). Claim 6 has been amended to specify that Applicant is referring to the number average molecular weight (Mn). Support for this amendment can be found throughout the specification and claims, wherein the number average molecular weight (Mn) is consistently specified.

Claim 26 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner has asserted that "[i]t is unclear how much, or how little, non-biodegradable polymer may be

present in the chewing gum for the gum to be considered 'substantially free' of said polymers." Applicant respectfully traverses this rejection.

The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. See MPEP § 2173.05(b). Specifically, it has been recognized that the term "substantially" is often used in conjunction with another term to describe a particular characteristic of the claimed invention, and that while it is a broad term, its use is generally acceptable. *In re Nehrenberg*, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). For example, in a case similar to the present one, the Court held that the limitation "which produces substantially equal E and H plane illumination patterns" was definite because one of ordinary skill in the art would know what was meant by "substantially equal." *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988).

In the present case, Applicant respectfully submits that one skilled in the art would know what is meant by the term "substantially free" (i.e., that the chewing gum contains no effective amount of non-biodegradable polymers, although a non-

functional trace amount may be present). The Examiner has provided no rationale as to why one skilled in the art would not know what is meant by the term, and instead appears to be stating that the term "substantially" is essentially always indefinite, which of course, is contrary to case law and MPEP guidelines. There is no analysis as to why the term "substantially" is indefinite in this particular instance, as opposed to those cases where the Court has found its use perfectly acceptable. As such, Applicant respectfully asks that this rejection be withdrawn.

**Rejections under 35 U.S.C § 103 (a)**

All claims were rejected under 35 U.S.C. § 103(a) primarily over either Bunczek et al. (U.S. Patent No. 6,013,287) or Cook et al. (U.S. Patent No. 6,441,126) and in some cases in view of various secondary and/or tertiary references. Applicant respectfully asks the Examiner to reconsider these rejections in view of the below Remarks.

**Bunczek et al.**

With respect to Bunczek et al., the Examiner argues that the wording "at least one" in claim 1 in Bunczek et al. indicates that there could be more than one. Also, the Examiner argues that the choice of Tg's and molecular weight, should "at least two" polymers be used, is based on the desired function of the polymers and

is a matter of no more than routine experimentation. However, Applicant respectfully submits that the differences between what is disclosed in Bunczek et al. and what is claimed in the pending Claim 1 (the only independent claim) are not obvious to the person skilled in the art.

Firstly, the task of matching at least two different polymers in a chewing gum formulation is indeed different from incorporating at least one polymer in a chewing gum formulation. The wording "at least one" is, of course, grammatically implying that there may be more than one. The specific and unexpected benefits from using at least two biodegradable polymers are, however, not disclosed or suggested anywhere in Bunczek et al. These benefits, as mentioned in the pending application, e.g., on page 3, line 14 – page 4, line 4 are, among others:

- a desirable texture;
- the possibility of providing a completely biodegradable chewing gum; and
- the possibility of obtaining specific release profiles, e.g., for the release of sweeteners and flavors, different from those obtained with conventional polymers

The mentioned benefits are also highlighted in the Examples of the pending application. Example 8 confirms the advantages in texture when using two different biodegradable polymers. The release properties are elucidated in Example 12.

The results are achieved by using two different polymers having different Tg's and differing in molecular weight. According to the Examiner's argument, the skilled person should realize, on the basis of the disclosure in Bunczek et al., that it is beneficial to use two biodegradable polymers, although all embodiments in Bunczek et al. comprise only one biodegradable polymer and additionally conventional polymers. Bunczek et al. clearly state that the incompatibility of their polyesters with other gum base ingredients may be overcome by modifying the composition of the polymer (Bunczek et al., column 9, lines 5-10). No teachings are given that such problems may be overcome by combining two or more biodegradable polymers with different Tg's and different molecular weights. This is exactly what has been done by Applicant.

Applicant respectfully submits that the Examiner's comments on obviousness in this regard are based on a simplification of the complex problems encountered when developing chewing gum and furthermore on an overestimation of the capacity of the skilled person. Bunczek et al. give no hints as to look at Tg or molecular weight when choosing a suitable polymer for adding to their gum base. Tg's are not given at all, and the molecular weight is merely stated as a means of characterization of the obtained polymers of examples B and C in Bunczek et al.

The Examiner's attention is also directed to the citations from the pending application given below under Cook et al., for some of the technical effects obtained by using the polymers recited in the pending Claim 1.

Bunczek et al. also clearly teach the combination of a biodegradable polyester with synthetic elastomer, e.g., Bunczek et al. column 9, line 62 - column 10, line 14. This would not lead the skilled person in the direction of the pending Claim 1. On the contrary, in line with the teachings of Cook et al. and Grijpma et al., gum bases and chewing gum comprising one single biodegradable polymer are taught. The Examiner's remarks contained in paragraph 18 of the outstanding Office Action are not completely understood, and the Examiner's attention is again respectfully directed to Applicants remarks below for comments on a similar remark by the Examiner regarding Cook et al.

Cook et al.

Turning to Cook et al. Applicant respectfully submits that the above arguments regarding Bunczek et al. are also applicable with respect to Cook et al. as well. The examples in Cook et al. merely show how to make crosslinked branched aliphatic polyesters. The difference between the gum base of Example 1B and the gum of Example 2B seems to be the choice of monomers in Examples

1A and 2A, respectively. No combination of polymers is taught, suggested or motivated. Molecular weights are mentioned only for synthetic conventional elastomers (Cook et al., column 8, lines 24 - 40). Tg's are not considered at all in Cook et al.

The skilled person reading Cook et al. will learn about the reactive extrusion of pre-gelled polymers as a suitable process for preparing crosslinked branched aliphatic polyesters. It is respectfully submitted by Applicant that the claimed chewing gum of the pending Claim 1 is not made obvious by the teachings of Cook et al.

The Examiner states: "However, given that the polyester polymers as taught by Cook et al. are to be used in chewing gum in place of conventional elastomers and elastomer plasticizers, the same function as claimed by Applicants, it would have been considered obvious to utilize polymers having molecular weights ( $M_n$ ) and  $T_g$ 's in the ranges as claimed, absent any convincing arguments or evidence to the contrary."

Applicant submits that it is not completely understood what is meant by the Examiner's claim for convincing arguments or evidence. Since it is not stated in Cook et al., what  $M_n$  and  $T_g$  is for the prepared polymers, Applicant is unable to

argue that these would have any specific values, should the skilled person try to combine two polymers. It is Applicant's view that the polymers taught by Cook et al. could have any value of Tg and (Mn).

The skilled person is completely on his/her own when:

- picking at least two polymers;
- choosing possible Tg's; and
- choosing possible molecular weights.

The below citations from the pending application state some of the technical effects achieved by Applicant when Mn and Tg are considered according to the pending Claim 1:

When applying relatively significant differences in molecular weight between the applied biodegradable polymers, an increased possibility of tuning with respect to both texture and for instance chewing gum release has been obtained.  
(PCT Application as filed, page 4, lines 27-29).

According to the invention, it has been realized that biodegradable chewing gum having a texture comparable to conventional chewing gum may be obtained, when at least two of the applied biodegradable polymers have different glass transition temperature. In other words, the applied biodegradable polymers form a hybrid polymer gumbase or chewing gum having at least two different properties with respect to the glass transitions temperature.



According to the invention, at least one of the applied biodegradable polymers may be applied for counteracting cold floating of the gumbase or the final chewing and at least one of the other may be applied for obtaining desired chewing gum properties with respect to texture.

In other words, according to the invention, it has been realized that the expected requirements with respect to the applied biodegradable polymers of a chewing gum may be significantly loosened when applying more polymers according to the invention.

Hence, according to the invention the important issue of facilitating shipping of the final product with respect to cold floating may even and unexpectedly, be dealt with by means of at least one stabilizing biodegradable polymers, e.g. a biodegradable polymer having a relatively high glass transitions temperature mixed with a further biodegradable polymer featuring another glass temperature than the stabilizing polymers. Typically, the at least one further biodegradable polymer may be chosen by e.g. an elastomer having a relatively low glass transition temperature.

Moreover, according to the invention, it has been realized that biodegradable polymers, when incorporated in a gum base or chewing gum composition reacts somewhat vulnerable compared to conventional polymers and it has moreover been realized that this vulnerability to softeners may be compensated when applying texture improving mixtures of at least two polymers having different glass transition temperature. Hence, the need for structure weakening softeners may be reduced due to the fact, that the texture is improved when compared to single Tg polymer blends of chewing gum.

(PCT Application as filed, page 5, line 29 – page 6, line 29).

In conclusion, the three major limitations of the pending Claim 1 are not disclosed in the prior art. The Examiner's contention that "at least one" implies "two" is obviously correct in general, but Applicant submits that substantial problems may arise for the skilled person when going from one to two

biodegradable polymers in a chewing gum. The skilled person can get no help in the prior art what Tg's and Mn's are concerned, so basically he/ she has an unlimited number of combinations from which to choose.

**Double Patenting Rejections**

With respect to the provisional nonstatutory obviousness-type double patenting rejection, Applicant will consider submitting the appropriate terminal disclaimer once allowable matter has been identified in the present case.

For the foregoing reasons, Applicant respectfully submits that all pending claims, namely Claims 1, 2, 4-6, 8, 10-13 and 15-66, are patentable over the references of record, and earnestly solicits allowance of the same.

Respectfully submitted,

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